Attachment C:

K073532

510(k) Summary

Manufacturer:	Technomed Europe Amerikalaan 71 6199 AE Maastricht Airport The Netherlands
Submitted by:	Technomed Europe Amerikalaan 71 6199 AE Maastricht Airport The Netherlands Tel.: (+31) 43-408 6868 Fax: (+31) 43-408 6888
Contact person:	Mr. Maurice Roost Manager Research & Development E-mail: mroost@technomed.nl
Date:	December 10, 2007
Proprietary Name:	Cutaneous Electrodes
Common/usual Name:	Disposable Adhesive Surface Electrodes
Classification Name:	Cutaneous Electrode is classified as class II per 21 CFR section 882.1320. Product code GXY.
Substantial Equivalence:	K000870: KM-10 Non-Sterile TENS Electrode K971914: TECA NCS Electrode System 2000
Device description:	Disposable Adhesive Surface Electrodes are non-invasive. Cutaneous devices are used in the acquisition of signals for the purpose of stimulating, monitoring and recording Electroencephalograph (EEG), surface Electromyography (EMG) and Evoked Potentials (EP). The electrodes are designed for single-patient/multiple application use and are very flexible. Because of the adhesive nature of the gel, no securing material is required for fixating the electrode to the patient's skin. There are two types of electrodes, one with fixed lead wire and the other without lead wire, tab electrodes. The electrodes with lead wire have a safety DIN 42802 connector, several lengths and color combinations. Tab electrode can be connected, using a lead wire with alligator clip, to the gel free contact strip at the electrode end.
Intended Use:	The Disposable Adhesive Surface Electrodes are intended for non-invasive use with recording and monitoring equipment, (active and reference), of Electromyography (EMG), Electroencephalograph (EEG) and Evoked Potentials (EP). The electrodes are designed for single-patient/multiple application use.

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Comparison to predicates:	The design, materials, chemical composition, packaging and other technological characteristics of the subject device is equivalent to those of the predicate devices.
Non-clinical data:	Technomed Europe has been bench testing the Cutaneous Electrodes to confirm performance characteristics of this device.
Conclusion:	The comparison to the predicate devices demonstrate that the Disposable Adhesive Surface Electrodes are safe and effective and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Technomed Europe
% Mr. Maurice Roost
Manager Research & Development
Amerikalaan 71
6199 AE Maastricht-Airport
Limburg
The Netherlands

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Re: K073532
Trade/Device Name: Disposable Adhesive Surface Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode.
Regulatory Class: Class II
Product Code: GXY
Dated: April 17, 2008
Received: April 21, 2008

Dear Mr. Roost:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

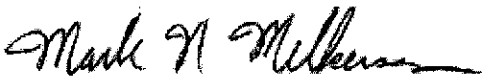
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073532

Device Name: Disposable Adhesive Surface Electrodes

Indications For Use:

The Disposable Adhesive Surface Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of stimulating/recording of biopotential signals. Electrodes are applied in the study of biopotentials such as Electroencephalograph (EEG), surface Electromyography (EMG), nerve conduction and Evoked potential signals (EP). Electrodes are non-invasive as they are applied to the patient's skin using a self-adhesive solid-gel surface. The electrodes are non-sterile and for single patient use only.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073532